REMARKS

The Office Action mailed March 12, 2004, has been received and reviewed. Claims 1 through 18 were currently pending in the application. Claims 7 through 17 were withdrawn from consideration as drawn to a non-elected invention. Claims 1 and 6 are canceled, claims 2, 3, 4 and 18 are amended, and claims 19 and 20 are added herein. Applicants note the requirement for restriction was made final in the Office Action and have amended the claims to comply therewith. All claims amendments are made without prejudice or disclaimer and applicants reserve the right to pursue the non-elected claims in one or more related applications. Applicants further reserve the right to petition the Commissioner, pursuant to 37 C.F.R. 1.144, to review the requirement for restriction.

Information Disclosure Statement

The Office Action states that only the first two pages of the Information Disclosure Statement filed December 21, 2001 was received by the Office. A duplicate copy of the December 21, 2001 Information Disclosure Statement is enclosed herewith as Exhibit B. It is respectfully requested the information thereon be made of record herein.

Sequence Rules Compliance and Drawing Changes

A Notice to Comply with the Sequence Rules is attached to the Office Action, requiring a new FIG. 1, which includes SEQ ID NOs, and a replacement Sequence Listing be provided. The required replacement FIG. 1 is submitted above and a replacement Sequence Listing is submitted herewith as Exhibit C. A computer readable copy of the Sequence Listing, and the required Statement accompany this response.

Amendments to the Specification

Amendment of the Specification was required in the Office Action to properly demarcate trademarks. Applicants have amended the specification herein in order to correct the misspelling noted in the Office Action and to properly demarcate trademarks. It is respectfully submitted that no further action is required on these points.

With respect to the requirement that the Abstract be corrected to include SEQ ID NOs, applicants note that a Preliminary Amendment was filed June 3, 2002, which amended the Abstract to include SEQ ID NOs. Applicants respectfully submit that no action is thus required. Should another copy of the Preliminary Amendment be required by the Office, Applicants will provide one.

Claim Objections

Claims 1 through 6 and 18 were objected to in the Office Action as assertedly drawn in the alternative to the subject matter of non-elected inventions. Claims 1 and 6 are canceled herein, rendering this objection moot as to them. Amended independent claims 2 and 18 are drawn to the elected invention, as are the claims dependent therefrom. It is respectfully requested the objection be withdrawn.

35 U.S.C. § 101 Rejections

Claim 6 was rejected under 35 U.S.C. § 101 as assertedly drawn to non-statutory subject matter. Claim 6 has been canceled herein, rendering this rejection moot.

35 U.S.C. § 112 Rejections

Claim 6 was rejected under 35 U.S.C. § 112 as assertedly failing to comply with the written description requirement, failing to comply with the enablement requirement and being indefinite. Claim 6 has been canceled herein, rendering these rejections moot.

Claim 5 was rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. The Office Action states:

> Claim 5 is drawn to a process for identifying transcription factors comprising providing cells having a nucleic acid sequence originating from a promoter region of the genes encoding Brachyruy, α4 integrin, follistatin, or E-cadherin, which comprises the sequence CACCTG-N-CACCTG, where N is a nucleotide sequence according to the specification at page 5, paragraph 0010. The promoter regions of the genes encoding Brachyruy, α4 integrin, follistatin, and E-cadherin have not been reported to comprise the sequence CACCTG-N-CACCTG, where N is a nucleotide sequence according to the specification at page 5, paragraph 0010, and

> there is no factual evidence of record to suggest otherwise. (Office Action at page 9).

Amended claim 5 recites a "process according to claim 4 wherein the promoter region is selected from the group consisting of Brachyury, a4-integrin, follistatin, and E-cadherin" but depends from amended claim 2 (through claim 4) which recites "providing cells with a nucleic acid sequence comprising a first SEQ ID NO: 1 and a second SEQ ID NO: 1 separated by N" (CACCT-N-CACCT). As set forth in paragraph [0010] of the present specification, the recited promoter regions all include the CACCT-N-CACCT sequence. Accordingly, it is respectfully requested this rejection be withdrawn.

35 U.S.C. § 102 Rejections

Claim 6 was rejected under 35 U.S.C. § 102 as assertedly being anticipated by Genetta et al., and by Sekido et al. Claim 6 has been canceled herein, rendering these rejections moot.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based Mak et al. (DNA CELL Biol. 15:1-8, 1996) in view of Sekido et al. (Genes Cells. .2:771-783, 1987).

Claims 1-4, 6 and 18 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Mak et al. (*DNA CELL Biol.* 15:1-8, 1996) ("Mak") in view of Sekido et al. (*Genes Cells.* .2:771-783, 1987) (Sekido). Claims 1 and 6 have been canceled rendering this rejection moot. With respect to the remaining claims, Applicants respectfully submit that the amended claims define over the combination suggested by the Office Action.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on

> applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

On page 13, the Office Action asserts that Mak discloses a yeast one-hybrid system by which mammalian cDNA libraries can be screened to isolate cDNA molecules encoding bHLH transcription factors that interact with E-box sites (see also Mak, page 7, second column, second paragraph). At page 19, the Office Action states that Mak does not teach a CACCT bait sequence, or two CACCT bait sequences separated by nucleotide spacer from 0 to at least 400 base pairs in length. The Office Action also states that Mak does not teach the use of this technique to isolate transcription factors with clusters of zinc fingers. The Office Action then asserts that Sekido discloses a promoter sequence with two CACCT sequences separated by a nucleotide from 0 to 400 bases, to which transcription factors bind. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to combine these references to generate the claims of the current invention.

Applicants respectfully submit that the instant claims are not obvious over Mak in view of Sekido. Amended claim 2 recites:

> A process of identifying transcription factors such as activators and/or repressors comprising:
> providing cells with a nucleic acid sequence comprising a first SEQ ID NO: 1 and a second SEQ ID NO: 1 separated by N as bait, wherein N is a spacer sequence.

Mak teaches a yeast one-hybrid system requiring (1) a hybrid expression library with a fusion protein formed with a transcription activating domain fused to random protein segments; and (2) a reporter gene containing the binding site of interest within its promoter region (see Mak, Figure 3). The yeast one-hybrid system of Mak is not screening a library for potential transcription factors but is merely looking for protein-DNA interactions using a candidate protein fused to a GAL4 transcription activation domain.

In Figure A, Sekido discloses a δEF1 repressor binding protein, with two clusters of zinc fingers, which form a single DNA binding domain which bind to only a single CACCT(G) sequence. The Office Action on page 13, paragraph 3, alleges that Sekido teaches an "enhancer DNA sequence compris[ing] two E-box sequences of CACCT separated by a nucleotide

sequence ranging in length from 0 to at least 400." Applicants respectfully disagree with this characterization. Instead, Sekido teaches that δEF1 forms a single DNA binding domain that is able to bind to the CACCT sequence of the δ-crystallin DC5 minimal enhancer region. Additionally, Sekido teaches that the single binding domain of δEF1 also recognized the E2-box sequence CACCTG. However, the δ-crystallin DC5 minimal enhancer region and the E2-box are not domains on a single enhancer sequence and are not separated by a nucleotide sequence from 0 to at least 400 base pairs. Furthermore, there is no suggestion of combining the δ-crystallin DC5 minimal enhancer region and the E2-box into one contiguous oligonucleotide. As such, Sekido teaches a repressor binding protein, with two clusters of zinc fingers, which form a single DNA binding domain which bind to only a single CACCT(G) sequence, not a nucleic acid sequence comprising a first SEQ ID NO: 1 and a second SEQ ID NO: 1 separated by N for use as bait. Therefore, it would not be obvious to one of ordinary skill in the art to use two CACCT sequences, separated by a spacer sequence, to isolate unknown transcription factors.

Accordingly, even if the teachings of these references were combined as suggested by the Office Action, the result would be a yeast one-hybrid system using fusion proteins of Mak, formed with a transcription activating domain that include a specific protein that binds to a single CACCT sequence. Such a combination does not teach each and every element of the instant claims. Applicants respectfully request this rejection be withdrawn and independent claim 2, with claims 3 and 4 dependent there from, be allowed.

Furthermore, independent claim 18, as amended herein, claims "providing cells with a nucleic acid sequence comprising twice a CACCT sequence (SEQ ID NO: 1) as bait for the screening of a library encoding potential transcription factors, wherein the at least twice a sequence is a first SEQ ID NO: 1 and a second SEQ ID NO: 1 separated by N." Similar to the reasoning discussed previously for claim 2, the combination of Mak and Sekido, suggested in the Office Action does not teach all the elements of claim 18. Accordingly, applicants respectfully request this rejection be withdrawn and independent claim 18 be allowed.

CONCLUSION

All claims are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,

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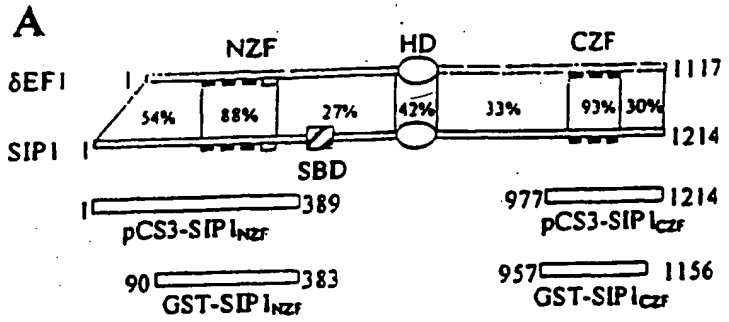
BLC/ps/bv
Document in ProLaw

ANNOTATED MARKED-UP DRAWINGS

Figure 1



B

SIP1NZF1 QLLTCPYCDRGYKRLTSLKEHIKYRHKNE (SEQ ID NO:50)

δ-EF1NZF1 QLLTCPYCDRGYKRFTSLKEHIKYRHKNE (SEQ ID NO:51)

SIP1NZF2 ENFSCPLCSYTFAYRTQLERHMVTHKPG (SEQ ID NO:52)

δ-EF1NZF2 DNFSCSLCSYTFAYRTQLERHMTSHKSG (SEQ ID NO:53)

SIP1NZF3 RKFKCTECGKAFKYKHHLKEHLRIHSGE (SEQ ID NO:54)

δ-EF1NZF3 RKFKCTECGKAFKYKHHLKEHLRIHSGE (SEQ ID NO:54)

SIP1NZF4 KPYECPNCKKRFSHSGSYSSHISSKKCI (SEQ ID NO:55)

δ-EF1NZF4 KPYECPNCKKRFSHSGSYSSHISSKKCI (SEQ ID NO:55)

SIP1CZF1 GHYACDLCDKTFQKSSSLLRHKYEHTGK (SEQ ID NO:56)

δ-EF1CZF1 GHYACDLCDKIFQKSSSLLRHKYEHTGK (SEQ ID NO:57)

SIP1CZF2 RPHQCQICKKAFKHKHHLIEHSRLHSGE (SEQ ID NO:58)

δ-EF1CZF2 RPHQCGICRKAFKHKHHLIEHMRLHSGE (SEQ ID NO:59)

SIP1CZF3 EKPYCDKCGKRFSHSGSYSQHMNHRYSY (SEQ ID NO:60)

δ-EF1CZF3 EKPYCDKCGKRFSHSGSYSQHMNHRYSY (SEQ ID NO:60)

C

SIP1NZF3-NZF4 CTECGKAFKYKHHLKEHLRIHSGEKPYECPNCKKRFSHSGSYSSHISSKKCI (SEQ ID NO:61)

SIP1CZF2-CZF3 CQICKKAFKHKHHLIEHSRLHSGEKPYQCDKCGKRFSHSGSYSQHMNHRYSYCK (SEQ ID NO:62)

δ-EF1NZF3-NZF4 CTECGKAFKYKHHLKEHLRIHSGEKPYECPNCKKRFSHSGSYSSHISSKKCI (SEQ ID NO:63)

δ-EF1CZF2-CZF3 CQICKKAFKHKHHLIEHMRLHSGEKPYQCDKCGKRFSHSGSYSQHMNHRYSYCK (SEQ ID NO:64)